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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/357,737	07/19/1999	ALESSANDRO SETTE	2473.0030005/PAJ/M-M	9669

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/357,737	SETTE ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *166,168,170,177 and 247* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *166,168,170,177,247* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/06 has been entered.

2. Claims 166,168,170,177,247 are under consideration.

3. The previously pending rejection of claims 166,168,170,177 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 10/031345 is withdrawn because said application has been abandoned.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 170,247 stand rejected under 35 U.S.C. 102(e) as being anticipated by Chien et al. (US Patent 6,150,087).

Chien et al. teach a peptide that comprises GVAGALVAFK (see column 27, second paragraph, AA1850-1900, wherein said peptide refers to amino acids in Figure 66 (sheet 107) and wherein said peptide comprises GVAGALVAFK). Chien et al. disclose said peptide conjugated to tetanus toxoid (see column 26, first paragraph) wherein tetanus toxoid inherently contains HTL epitope(s). The "conjugate is" and "epitope is linked" are considered open language (equivalent in scope to comprising) and therefore the claim encompasses GVAGALVAFK attached to other HCV amino

acids and further attached to tetanus toxoid. The peptide comprising the peptide recited in the claims is directly linked to tetanus toxoid.

Regarding applicants comments, the "conjugate is" and "epitope is linked" are considered open language (equivalent in scope to comprising) and therefore the claim encompasses GVAGALVAFK attached to other HCV amino acids and further attached to tetanus toxoid as per taught by Chien et al. The peptide comprising the peptide recited in the claims is directly linked to tetanus toxoid.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 166,168,170,177,247 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (US Patent 6,150,087) in view of Berzofsky et al. (US Patent 5,980,899) in view of Guo et al. Applicants arguments have been considered and deemed not persuasive.

Chien et al. teach a peptide comprising the peptide of claim 166 (see column 27, second paragraph, AA1850-1900, wherein said peptide refers to amino acids in Figure 66 (sheet 107) and wherein said peptide comprises GVAGALVAFK). Chien et al. teach said peptide can be conjugated to tetanus toxoid (see column 26, first complete paragraph). Virtually any intact immunogenic molecule will contain at least one helper

cell epitope. Chien et al. also teach a composition containing said peptide and a carrier (see column 26, first complete paragraph). Chien et al. do not teach the peptide of claim 166/168. Berzofsky et al. teach that it is desirable to identify CTL epitopes found in HCV (see column 2, fourth paragraph). Guo et al. teach that CTL recognize viral peptides complexed with MHC (see page 364, first column, last sentence continued on next page). Guo et al. teach that said peptides which bind HLA-Aw68 generally are 9 to 11 amino acids with a V at P2 (position 2) and a K at the c-terminal position. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Chen et al. teach an immunogenic HCV peptide containing GVAGALVAFK, whilst Berzofsky et al. teach that it is desirable to identify CTL epitopes found in HCV and Guo et al. teach that CTL recognize viral peptides complexed with MHC and that peptides which bind HLA-Aw68 generally are 9 to 11 amino acids with a V at P2 (position 2) and a K at the c-terminal position. One of ordinary skill in the art would have been motivated to create the claimed peptide to screen for HCV peptides which were recognized by CTL because Berzofsky et al. teach that it is desirable to identify CTL epitopes found in HCV and Guo et al. teach that CTL recognize viral peptides complexed with MHC and that peptides which bind HLA-Aw68 generally are 9 to 11 amino acids with a V at P2 (position 2) and a K at the c-terminal position.

Regarding applicants comments, one of ordinary skill in the art would have been motivated to create the claimed peptide to screen for HCV peptides which were recognized by CTL because Berzofsky et al. teach that it is desirable to identify CTL epitopes found in HCV and Guo et al. teach that CTL recognize viral peptides complexed with MHC and that peptides which bind HLA-Aw68 generally are 9 to 11 amino acids with a V at P2 (position 2) and a K at the c-terminal position. Regarding applicants comments about Berzofsky et al., the Chien et al. reference discloses that the sequence comprising GVAGALVAFK contains a HCV epitope (see column 27, first paragraph). Regarding Berzofsky et al. and NS5, Berzofsky et al. does not teach that NS5 provides the only CTL epitope in HCV. Berzofsky et al. indicate that CTL epitopes would be present in other regions of HCV (for example see column 13, first paragraph and column 12, second paragraph). Regarding applicants comments about Guo et al. and 9mer peptides, said comment is made regarding the prior art. It is not a comment

regarding the results disclosed by Guo et al. Guo et al. teach that peptides which bind HLA-Aw68 generally are 9 to 11 amino acids with a V at P2 (position 2) and a K at the c-terminal position (see abstract).

Regarding applicants comments about "inherency" and the alleged unexpected properties of the peptide of claim 166, the MPEP section 2145 (II) states:

II. ARGUING ADDITIONAL ADVANTAGES OR LATENT PROPERTIES
Prima Facie Obviousness Is Not Rebutted by Merely Recognizing Additional Advantages or Latent Properties Present in the Prior Art
Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979) (Claims were directed to grooved carbon disc brakes wherein the grooves were provided to vent steam or vapor during a braking action. A prior art reference taught noncarbon disc brakes which were grooved for the purpose of cooling the faces of the braking members and eliminating dust. The court held the prior art references when combined would overcome the problems of dust and overheating solved by the prior art and would inherently overcome the steam or vapor cause of the problem relied upon for patentability by applicants. Granting a patent on the discovery of an unknown but inherent function (here venting steam or vapor) "would re-move from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art." 596 F.2d at 1022, 201 USPQ at 661.); In re Baxter Travenol Labs., 952 F.2d 388, 21 USPQ2d 1281 (Fed. Cir. 1991) (Appellant argued that the presence of DEHP as the plasticizer in a blood collection bag unexpectedly suppressed hemolysis and therefore rebutted any prima facie showing of obviousness, however the closest prior art utilizing a DEHP plasticized blood collection bag inherently achieved same result, although this fact was unknown in the prior art.).
"The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985) (The prior art taught combustion fluid analyzers which used labyrinth heaters to maintain the samples at a uniform temperature. Although appellant

showed an unexpectedly shorter response time was obtained when a labyrinth heater was employed, the Board held this advantage would flow naturally from following the suggestion of the prior art.). See also Lantech Inc. v. Kaufman Co. of Ohio Inc., 878 F.2d 1446, 12 USPQ2d 1076, 1077 (Fed. Cir. 1989), cert. denied, 493 U.S. 1058 (1990) (unpublished — not citable as precedent) ("The recitation of an additional advantage associated with doing what the prior art suggests does not lend patentability to an otherwise unpatentable invention.").
In re Lintner, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) and In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990) discussed in MPEP § 2144 are also pertinent to this issue.

In addition, the peptide of claim 166 is found in the larger peptide taught by Chien et al. (associated with other naturally occurring HCV amino acids) wherein Chien et al. teach that said larger peptide is immunogenic. Furthermore, the functional attributes of the peptide of claim 166 would presumably be present in the peptide of Chien et al. in that said larger peptide would be processed in vivo to yield the peptide of claim 166. Regarding applicants comments about Yewdell et al., there is no evidence of record that suggests that the peptide taught by Chien et al. contains another immunodominant epitope that would suppress the response to the peptide recited in the claims. Applicants arguments also ignore the teachings of Guo et al. Guo et al. teach that CTL recognize viral peptides complexed with MHC (see page 364, first column, last sentence continued on next page). Guo et al. teach that said peptides which bind HLA-Aw68 generally are 9 to 11 amino acids with a V at P2 (position 2) and a K at the c-terminal position. The teachings of Guo et al. provide a reasonable expectation of success of obtaining the claimed peptide. The MPEP section *2143.02* indicates that obviousness requires only a reasonable expectation of success.

Reasonable Expectation of Success Is Required
OBVIOUSNESS REQUIRES ONLY A REASONABLE EXPECTATION OF SUCCESS
The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d

1091, 231 USPQ 375 (Fed. Cir. 1986) (Claims directed to a method of treating depression with amitriptyline (or nontoxic salts thereof) were rejected as prima facie obvious over prior art disclosures that amitriptyline is a compound known to possess psychotropic properties and that imipramine is a structurally similar psychotropic compound known to possess antidepressive properties, in view of prior art suggesting the aforementioned compounds would be expected to have similar activity because the structural difference between the compounds involves a known bioisosteric replacement and because a research paper comparing the pharmacological properties of these two compounds suggested clinical testing of amitriptyline as an antidepressant. The court sustained the rejection, finding that the teachings of the prior art provide a sufficient basis for a reasonable expectation of success.); Ex parte Blanc, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Claims were directed to a process of sterilizing a polyolefinic composition with high-energy radiation in the presence of a phenolic polyester antioxidant to inhibit discoloration or degradation of the polyolefin. Appellant argued that it is unpredictable whether a particular antioxidant will solve the problem of discoloration or degradation. However, the Board found that because the prior art taught that appellant's preferred antioxidant is very efficient and provides better results compared with other prior art antioxidants, there would have been a reasonable expectation of success.).

In addition, the Yewdell et al. publication is published after the effective filing date of the instant invention and is therefore not germane to the state of the art at the time the invention was made. The MPEP section 2143.02 discloses:

PREDICTABILITY IS DETERMINED AT THE TIME THE INVENTION WAS MADE

Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. Ex parte Erlich, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986)

Furthermore, if the peptide recited in the claims is an actual physiologically relevant CTL epitope than the larger molecule containing said epitope must be processed in vivo to result in said peptide. In addition, the specification discloses that the peptide can be 30 amino acids long (see page 37) and conjugated to a HTL, indicating that according to the teachings of the specification, there is no criticality regarding the length of the peptide. Regarding Del Val et al. said reference refers to a peptide containing a CTL peptide and exogenous sequences not naturally found associated with the CTL peptide. The peptide taught by Chien et al. contains only naturally occurring HCV sequences. Regarding Eisenlohr et al., said reference actually teaches that flanking sequences can also positively effect the presentation of an immunogenic peptide (se page 484, first column, last paragraph). There is no evidence of record that addresses the effect of the flanking sequences found in the peptide disclosed by Chien et al. Furthermore, the specification, page 12, lines 15-22 indicates that the peptide can be of a variety of lengths that are longer than the actual size of the peptide bound by HLA indicating that the inventors of the instant application did not believe that such additional amino acids would generally pose problems.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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